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Description

IMPROVED ORTHOTIC DEVICE

BACKGROUND OF INVENTION

[0001] The feet constitute a most remarkable foundation for the human body. Academically the foot is referred to as a mobile adapter and propulsive lever. It is a portable foundation that is a most effective ambulatory, shock absorbing and propulsive system, consisting of 28 interdependent bones including the tibia and fibula to compose the essential ankle articulation.

[0002] As the foundation for the human body, the foot joint alignments and dynamic stability directly affects the alignment, posture and dynamic performance potential of the whole body. Proper alignment of the primary weight bearing joints is essential for the optimal function of the foot. The feet are designed to operate and work with irregular ground engaging surfaces. However through more recent generations the feet are exposed more and more to flat and hard surfaces. Further, they are contained within shoes that exacerbate over adaptation. It is believed that

this results in excessive pronation and hyper mobility pathologies with the more common less than functionally stable feet. Most feet over adapt and others do not adapt enough. These feet constitute the majority. Normal feet appear to be in a minority.

[0003] The most commonly used method of providing protection for feet or other parts of the body such as normal or amputated extremities or for joints is to provide a cushion of resilient material underneath the extremity or around the joint. Such a cushion simply provides general padding beneath or around the relevant part and does not attempt to: provide any dynamic support or protection. As used herein, the term dynamic support and protection means support and protection which is capable of altering in response to movement of the relevant part, so that the part is supported and protected in most or all of its normal range of movements.

[0004] Underfoot orthotics have been used popularly for the past 30 years to help stabilize the pronatory motions and offer the foot a personalized and familiar surface against which to balance and perform. These orthoses are molded and fabricated according to a wide variety of theories, procedures and materials.

[0005] The state of the art until now has been to cast and mold the plantar shape of each foot in one static position, directly or indirectly, by transferring to thermally molded rigid or more elastic plastic or softer foam. The foot then has to adapt to this one static shape, regardless of activity or dynamic. Softer foams are often used to cover the specific shape to more comfortably ameliorate the shape that cannot adapt to the constantly changing shapes of the plantar aspect.

[0006] The plastics and foams unfortunately deteriorate and lose their supportive shapes. In most cases the foot is supported by a thermally molded rigid plastic or foam that represents the plantar surface of the foot in the one static molded position. However, the bones of the foot are in constant motion and every lightest change in position reflects a change in the plantar aspect shape. Therefore, with every weight bearing change, the foot dynamic is trying to adapt over this rigid singular static position shape. Therefore these supports are rarely comfortable and can create problems and injuries that are reflected in other parts of the anatomy. Select foam interfacing, or more elastic plastics are usually used to ameliorate the discomforts between the devices and the foot.

[0007] For example, U.S. patent No. 6,233,847 (Brown) dated 22 May 2001 discloses a footwear insole which consists of a soft cushioning foam blank to underlie the foot in order to provide general padding for the foot. A semi-rigid cap underlying the heel end of the base of the blank provides some additional support for the blank, and hence for the foot also, in that region. However, this design makes no provision for the changing cushioning requirements of a foot during normal movement, e.g.,walking, running.

[0008] It also is known to use a moldable foam or sheet plastics blank which can to some extent be customized to the particular foot shape of an individual user. In general, such blanks are heated to a temperature at which the foam plastics softens, and are placed in the shoe and allowed to harden while the user stands in the shoe with the foot in a predetermined position.

[0009] Another type of customized insole is disclosed in U.S. patent No. 5,647,147 (Coomer) dated 15 July 1987. This orthotic insole incorporates an envelope lying beneath at least part of the foot. A two-part resin is injected into the envelope with the foot of the user in place in the shoe and allowed to cure to provide a customized supporting surface beneath the foot.

[0010] Such molded insoles provide better support for a foot than a simple pad of cushioning foam, but have the drawback that the insoles are molded with the foot in one particular position and therefore do not offer ideal support to the foot in other positions. Thus, as the foot flexes and changes shape, as it does in every activity such as during walking, running or jumping, the foot is not correctly or adequately supported. Indeed, an insole molded to support a foot in a single position may be uncomfortable, as the foot attempts to move dynamically over and around this one predetermined shape or even tend to unbalance the person, when the foot is in a different position.

[0011] Existing orthotic systems represent the foot or other extremity in only one frozen neutral position, usually positioned in unweighted neutral subtalar joint and locked talo-navicular (mid-tarsal) joint alignment. Other molding methods tend to capture the foot shape in an already deformed and compensated position from the ideal anatomical shape that is normally typical just prior to weight bearing.

[0012] Other prior art designs seek to provide the dynamic cushioning and support by including in the insole a fluid filled cushion; the fluid may be a liquid or a gas. For example,

U.S. patent Nos. 6,055,746 (Lyden) dated 2 May 2000, No. 6,158,149 (Rudy) dated 12 December 2000 and No, 6,178,663 (Schoesler) dated 30 January 2001 all disclose insoles of this general type.

[0013] Although a fluid filled cushion has the potential to provide effective cushioning, this design has a number of inherent problems. For example, if the cushion is very thick and the fluid compressible, it provides excellent padding but very poor stability. The user of this type of cushion is effectively trying to balance on a ball of air or liquid. However, if the cushion is thin, obviously it provides much less effective padding.

[0014] Another example of problems with the fluid filled cushions is if the fluid is virtually incompressible and the fluid envelope does not allow the fluid to move sufficiently when pressure is applied by the foot, the cushion provides very little effective or biomechanically functional padding. It follows that it is necessary for the fluid envelope to be designed so that fluid can move under applied pressure, but if the fluid is allowed to move too freely, again there is little effective padding or orthotic support for the foot and the design has poor stability, since the foot is pressing on a fluid which moves out from under the foot rapidly. Thus,

it is necessary to restrict the flow of fluid from one area of the fluid envelope to another.

[0015] The above mentioned designs proposed a variety of solutions to these problems in the form of fluid flow restrictors in the cushions or seams formed in the cushions to direct flow. However, none of the prior proposals overcomes the problem of restricting or directing fluid flow within the cushion to provide an optimum level of padding without sacrificing stability. In particular, the prior proposals fail to make adequate provision for the recirculation of the cushioning fluid, so that a foot of the user does not press the cushioning fluid away from the areas of higher pressure with the first few steps, and thereafter reduce the cushioning and orthotic supporting ability of the insole because the fluid cannot return to the higher pressure areas.

[0016] Another problem that exists with typical orthotic systems is the lack of stability in the heel portion of a shoe during the heel strike. This is the point at which the foot is most vulnerable, during the weight of the heel. Most stabilizing systems are static and uncomfortable or are ineffective.

[0017] There currently exists a problem in providing an orthotic system that will that adapt to and works continuously with

the most efficient dynamic and supportive needs of the foot or other extremity.

SUMMARY OF INVENTION

[0018] The present invention resolves the above cited problems of existing orthotic supportive systems with a dynamically responsive orthotic support that adapts to and works continuously with the most efficient dynamic and supportive needs of the foot. The result is a complimentary suspension and energy transmission system.

[0019] A preferred embodiment of the present invention provides a prosthesis with perpetually orthotically dynamic molding compound. The system is able to dynamically provide support to the area of the extremity at the time when the support is needed.

[0020] The system of a preferred embodiment includes a unique compound and containment method for interfacing anatomical parts to create orthotically dynamic molding prostheses and orthotics.

[0021] The containment system consists of a retaining sack that manages a newly formulated and proprietary dynamic molding compound to interface between the anatomical extremities, limbs and articulations of the human or animal anatomy and a premolded prosthetic counter frame or

protective shell. The pressures and motions exerted by the activity of the anatomy continuously kneads, massages and irrigates the compound against proprietary pre molded shapes of the prosthesis or orthotics to generate optimum support, stability, control, performance and comfort at all times in every physical activity.

[0022] The compound is formulated to mold and disperse spontaneously when heated briefly in a microwave oven, or more slowly with other heat sources. The appropriate viscosity is derived according to the particular dynamic demands of each activity and the pressures exerted by the respective anatomy interfacing the prosthesis or orthotics.

[0023] The compound accumulates and then slowly discharges heat at a predetermined rate. The compound stabilizes warmth by thermal exchange with the respective anatomy as the accumulated heat slowly discharges.

[0024] Additional compound can be manually injected or withdrawn through an access port hole under the medial arch with a single barrel syringe like injector, to accommodate higher arch morphologies. To reduce the volume for lower arches the compound can be heated and massaged out through the port hole.

[0025] A preferred embodiment of the present invention provides

an orthotic device for providing cushioning and support for parts of the body. The device includes a rigid or semi rigid counter frame which is molded to a predetermined shape. A flexible sack containing moldable paste is arranged to overlie at least part of said counter frame. The surface of the counter frame in contact with the sack is contoured so as to control the directions of flow of the moldable paste when pressure is applied by a part of the body to the surface of the sack opposite to the counter frame in use. A contact layer is used to overlie the sack.

[0026] The contact layer and the sack may be incorporated into a single unit, or a separate contact layer may be arranged to overlie the sack. The sack may be dimensioned to the size of the whole of the part of the body to be cushioned, or may be smaller in size.

[0027] The device of the present invention initially has been developed for use as a footwear insole, and will be described with especial reference to this application. However, it will be appreciated that the device of the present invention also may be used to support and cushion any of a number of parts of the body, e.g., normal or amputated extremities, joints, heads or backs.

[0028] It is envisaged that the device of the present invention

would be suitable for use as a liner for a prosthesis, as a support for a damaged (injured) joint such as an ankle joint, as a liner for protective padding or a helmet, boot and shoe, or as a liner for a saddle for a pack or riding animal.

[0029] If the device of the present invention is used as a footwear insole, the base comprises a counter frame, which may extend the full length of the insole or approximately three- quarter length; the upper surface of the counter frame is contoured and shaped to support the foot and to direct the moldable material to flow in the desired manner. The counter frame may incorporate a heel stabilizer or may be used with or without a separate heel stabilizer. The counter frame contours are designed to deform under load in such a way that the contours direct the flow of paste between the foot and the counter frame. The heel stabilizer may be used independently of the counter-frame, in combination with a conventional insoleThe flexible sack is dimensioned so as to overlie the counter frame. Preferably, the contact layer extends the full length of the insole and is formed of a soft and deformable sheet, which deforms readily under pressure by the foot of the user.

[0030] Preferably, the counter frame, flexible sack and contact layer are permanently secured together to form a single unit.

[0031] The device of the present invention may be used as a separate insertable device for insertion into, e.g., footwear or the contact surface of a prosthesis, or may be built into the article with which it is to be used.

[0032] By way of example only, a preferred embodiment of the invention in the form of a footwear insole will be described in detail with reference to the accompanying drawings.

Brief Description of Drawings

[0033] Figure 1 is an isometric view of a preferred embodiment of the invention, in the form of an insole for the left foot.

[0034] Figures 2 - 5 are diagrammatic side views showing a foot in combination with an orthotic system of the embodiment of Figure 1 going through a typical sequence of positions which occur during normal walking.

[0035] Figure 6 is a cross section on lines 6 - 6 of Figure 1, that relates to the foot and orthotic in the position of Figure 2 showing the orthotic insole substantially undeformed.

[0036] Figure 7 is a cross section on lines 7 7 of Figure 1, that relates to the foot and orthotic in the position of Figure 3

showing the orthotic insole slightly deformed.

[0037] Figure 8 is a cross section on lines 8 - 8 of Figure 1, that relates to the foot and orthotic in the position of Figure 3 showing the orthotic insole increasingly deformed.

[0038] Figure 9 is a cross section on lines 9 - 9 of Figure 1, that relates to the foot and orthotic in the position of Figure 3 showing the orthotic insole increasingly deformed.

[0039] Figure 10 is a cross section on lines 10 - 10 of Figure 1, that relates to the foot and orthotic in the position of Figure 4 showing the orthotic insole increasingly deformed.

[0040] Figure 11 is a cross section on lines 11 - 11 of Figure 1, that relates to the foot and orthotic in the position of Figure 5 showing the orthotic insole increasingly deformed.

[0041] Figure 12 is an isometric view of the under side of a heel stabilizer for the right foot.

[0042] Figure 13 is a perspective view of a heel stabilizer and insole of a preferred embodiment of the present invention.

[0043] Figure 14 is a perspective view of the heel stabilizer of Figure 13.

[0044] Figure 15 is a side view of the heel stabilizer of Figure 13.

[0045] Figure 16 is a perspective view of the heel stabilizer of Figure 13.

[0046] Figure 17 is a sectional view of the heel stabilizer of the

embodiment of Figure 13 unweighted.

[0047] Figure 18 is a sectional view of the heel stabilizer of the embodiment Figure 13 weighted.

DETAILED DESCRIPTION

[0048] The present invention, in a preferred embodiment, provides devices and methods for providing dynamic molding of orthotic devices. A preferred embodiment of the present invention is described below. It is to be expressly understood that this descriptive embodiment is provided for explanatory purposes only, and is not meant to unduly limit the scope of the present invention as set forth in the claims. Other embodiments of the present invention are considered to be within the scope of the claimed inventions, including not only those embodiments that would be within the scope of one skilled in the art, but also as encompassed in technology developed in the future.

[0049] Underfoot orthotics are used to help describe one application of the principles though the invention is not confined to this specialty application. The same principles can be applied by the designer to create orthotically dynamic molding support in a large variety of applications in all types of prostheses. A few such applications are therapeutic and protective equipment, seats, helmets,

footwear, knee and ankle pads, and saddle pads. The intention is to achieve the most refined levels of support, comfort and performance in all physical activities. The lingering warmth and thermal exchange qualities, when combined with assorted orthotically dynamic molding capacities, also has substantial therapeutic and medical applications.

[0050] *Overview of the Dynamic Orthotic Molding System*

[0051] A preferred embodiment of the present invention is illustrated in Figures 1 - 11 of the drawings. The dynamic orthotic molding system of this preferred embodiment includes a footwear insole 10 having a base or counter frame 12, a contact layer 14 and two separate flexible sacks 16, 18 containing a moldable paste and sandwiched between the base 12 and the contact layer 14.

[0052] In an overview of the preferred embodiment of the present invention, a dynamic molding prosthesis or orthotic is provided that constantly generates natural and locked supportive shape definitions at every moment and during every movement. The combination of the movement of the moldable paste due to the kneading action of the foot and the pre-molded counter frame shape as well as the viscosity and elasticity of the moldable paste pro-

vide the dynamic changing of the supportive shape during these movements. It is to be expressly understood that while descriptive embodiments are provided herein for explanatory purposes, the claimed inventions are not to be limited by these descriptive embodiments.

[0053] The counter frame 12 of this preferred embodiment extends the full length of the insole and forms the bottom of the insole. The counter frame 12, of this preferred embodiment, is a one-piece molding of a compression-molded foam which is elastic but substantially non-compressible material, formed with a lower surface, which corresponds in plan to the shape of the foot, and side walls 24 which extend upwards around the lower surface 22 to fit around the sides and rear most portion of the foot. This counter frame as well as alternative embodiments are discussed in greater detail below.

[0054] The lower surface 22 of the counter frame 12 is formed with a thinned or cut-out portion 26 in the shape of an elongated numeral 8. One loop 28 of the portion 26 lies underneath the area of greatest pressure applied by a heel of a user. The other loop 30 of the portion 26 lies in a position under the metatarsal or transverse arch. The thickness of the counter frame 12 over the area of the thinned

portion 26 is reduced, so that the counter frame has greater flexibility in this area, and can flex downwards, (i.e., towards the ground surface underneath the insole) when pressure is applied by the foot during walking.

[0055] Flexible ribs (shown in Fig. 1 only) are formed on the lower surface 22 of the counter frame, partially surrounding the portion 26. Three such ribs 50, 52, 54 are depicted in broken lines in Fig 1 but it must be emphasized that the ribs 50, 52, 54 are exemplary only: the number, thickness, length and positioning of the ribs can be varied widely, to suit particular requirements.

[0056] The ribs project outwards from the plane of the surface 22 and thus support the insole upon the underlying boot or shoe. In particular, the ribs suspend the portion 26, to keep the groove formed by the portion 26 open so that in use the moldable paste can move along the portion 26, as hereinafter described.

[0057] The insole can be made stiffer and more supportive by increasing the number or width of the ribs or by decreasing the spacing between the ribs. Conversely, the insole can be made softer and more flexible by using fewer ribs or by making the ribs narrower or more widely spaced.

[0058] It is envisaged that the counter frame 12 could be formed

with a plurality of relatively long, closely spaced ribs, and the technician fitting the insole to a customer could trim or remove ribs as necessary to achieve the described performance characteristics for the insole.

[0059] As shown in Figures 1, 2, 5 and 6 -11, the back wall 32 of the counter frame 12 and the adjacent rear most portions 34, 36 of the side walls 24 are comparatively high, to cup the heel of the wearer and provide stable support for the heel. As shown in the cross sectional views 7 and 8, the portion 38 of the walls 24 which extend along the inner side of the foot, i.e., adjacent the inner arch of the foot are higher than the portion 40 of the wall on the opposite side of the counter frame, to give firm and elastic support to the arch. The fact that the counter frame has raised side walls assists in directing the flow of the moldable paste by the shape and dynamics of the foot, as described in detail hereinafter. The side walls 24 gradually decrease in height towards the toe of the insole, so that the forward portion of the insole from approximately the midpoint of the foot onwards is almost flat.

[0060] The upper surface of the counter frame 12, i.e., the surface which in use is in contact with the underside of the sack 16 of moldable paste is formed with a central promi-

nence 42 which corresponds in position to the thinned portion 26 and extends substantially the full length of the thinned portion, gradually decreasing in height from the heel to the toe of the insole. Corresponding channels 44, 46 extend along the length of the insole along each side of the prominence 42, but the channel 46 along the inner side of the insole is substantially deeper so that in use more of the moldable paste lies in this area to cushion the arch and to allow free flow of the paste. As the prominence 42 flattens towards the toe of the insole, so the channels 44, 46 also decrease in depth, as is visible from Figures 10 and 11.

[0061] Two separate sacks of moldable paste 16, 18 lie on top of the counter frame 12. The first sack 16 covers a major portion of the counter frame, as shown in Fig. 1. The sacks 16 and 18 may be secured in position relative to the counter frame 12 in any suitable way, e.g., by securing the perimeter of each sack to the underlying surface of the counter frame or the contact layer 14. The moldable paste may be free to move within each sack without restriction, or the sacks may be subdivided e.g., by vertical stitching to provide specific flow channels for the moldable paste, as in another preferred embodiment of the present inven-

tion. In this preferred embodiment, the sacks are not subdivided in any way. Instead it is the relationship of the foot dynamics and the base contours that control the flow of the paste. This ensures that the paste can move freely in use and can recirculate easily.

[0062] The sack 16 extends from just in front of the heel area, (the calcaneus contact point) to just short of the ball of the foot, but with a rear extension 48, 50 on each side of the thinned portion 26. The sack 16 ends just beyond the forward end of the thinned portionThe sack 18 is roughly angularly shaped and covers the area to and under the metatarsal heads, under the base of the toes. For less demanding applications where a lower level of cushioning is acceptable, a layer of cushioning foam could be substituted for sack 18.

[0063] Sack 16 and sack 18 each is fitted with an insertion valve or plugged opening 56, 58 through which additional paste can be inserted into or withdrawn from the sack, to suit the supportive requirements of a particular user.

[0064] The contact layer 14 is a flat sheet of material of the same shape in plan as the upper surface of the counter frame 12. The contact layer 14 may be made of one or more layers of any suitable material, e.g., leather, fabric, foam or

plastics material and may include an additional cushioning layer.

[0065] The counter frame sacks 16 and 18 and contact layer 14 may be secured together using any suitable known techniques (e g sewing, welding, gluing). Also, the sacks 16 and 18 may be formed integrally with the contact layer. The sheet cushioning material sold under the U.S. trade mark SKYDEX may be a particularly suitable material for the contact layer 14, and it is envisaged that the material also could be used to form an additional or substitute covering layer lying between the upper surface of the counter frame 12 and the sacks 16 and 18.

[0066] *In use*The above insole will now be described in use; the deformation which the insole undergoes throughout a normal walking gait cycle in use is shown by a comparison of Figures 6 with Figures 7 - 11, and the position of the foot during each stop is shown by the sequence of Figures 2 - 5. In Figures 2 - 5, the pressure exerted by the wearers weight on the insole and ground are indicated by broad headed arrows.

[0067] Referring first to Figures 2 and 6, at the first part of a step (heel strike), the foot is angled at an acute angle to the surface of the ground, with only the heel touching the

ground, as shown in Fig. 2. At this stage, the walker is transferring all his weight to that foot; normally the foot is slightly supinated and adapts immediately to the underlying ground by pronating inwards towards the medial aspect as the weight on the foot increases.

[0068] As shown in Figure 6 as the heel strikes, the thinned portion 26, which is directly under the center of the heel, flattens out from the position of Figure 6 to that of Fig. 7. This reduces the height of the prominence 42 and also causes the sides 34, 36 of the counter frame immediately adjacent the heel area to move, cupping the sides of the heel and thus stabilizing the calcaneus maintaining the integrity of the shock absorbing fat pad of the heel and shape while helping to reduce slipping of the heel relative to the insole or the shoe sole.

[0069] The ribs 50, 52, 54 are not shown in Figures 6 - 11, but the arrows X and Y indicate approximately the positions of the ribs. It will be noted that there is no paste in part of this area, the sack 16 does not extend over most of the heel portion. As shown in Fig. 2, the moldable paste in the sacks 16 and 18 is substantially uncompressed at this stage.

[0070] Fig. 3 shows the next stage in the step, in which the

weight bearing on the foot is complete, and the pronatory motion ends. The modification of the insole at this stage is shown by the contrast between Figures 7 9. A comparison of Figures 7 - 9 with the corresponding Figures 10 - 11 shows how the increase in pressure on the portions of the insole indicated by the section lines flattens the prominence 42 and starts to compress the moldable paste in the vicinity of the prominence 42. Further, the pressure exerted by the wearer curves the sides of the insole drawing the sides of the insole in towards the foot to give additional support.

[0071] The curving of the sides of the insole in this way tends to push the moldable paste from the outer edges of the insole back towards the center line of the insole; this helps to counteract the tendency of the moldable paste to move towards the outer edges of the insole due to the greater pressure of the foot in that area.

[0072] It is at this stage that the wearer needs cushioning under the arch, since, as shown by the broad headed arrows in Fig. 3, much of the weight of the wearer is on that area of the foot. The cushioning effect is achieved by the ability of the moldable paste to move, and it will be noted that the moldable paste is encouraged to move along the length of

the insole by the depression of the prominence 42; this is facilitated by the presence of the thinned area 26.

[0073] Fig. 4 illustrates the propulsive phase of the step, as the heel lifts and all the weight bearing is guided by the counter frame deformation and paste displacement to follow along the neutral axis of normal weight bearing in the gait cycle to the center of the metatarsal heads.

[0074] A comparison of Figure 10 and 11 show how the prominence 42 is flattened in this area, which is proximal to the end of the sack 16. The wearer pressure applied adjacent the end of the sack 16 now pushes the moldable paste back towards the heel of the insole, thus reversing the direction of flow of the moldable paste which occurred during the earlier stages of the step. The fact that the sack 16 ends at about this point means that the moldable past cannot be pushed further forward towards the toe of the insole, where it would tend to lodge permanently, thus rapidly reducing the cushioning effect of the insole.

[0075] Fig. 5 shows the final stage of the step. This is the propulsive toe off stage in which the pressure of the wearer is on the ball of the foot and upon the toes, propelling the wearer forwards. At this stage, cushioning is required under the base of the toes; this is supported by

the sack 18. The balance of the user is easily affected by the amount of cushioning in this area, too much cushioning in the sack 18 will not only be uncomfortable but also will tend to unbalance the skeletal alignment of the wearers foot. As shown in Figure 11, the sack 18 is used simply to provide a small amount of stable cushioning in this area.

[0076] The sequence of the step is now completed and this sequence is repeated by the other foot. It will be appreciated that the moldable paste not only offers cushioning without instability, but also is automatically recirculated by the wearer, so that when the wearer takes the next step, the moldable paste has returned to the initial position so that it offers continual cushioning and is neither compressed nor distorted by prolonged use.

[0077] In use, the above described structure provides a unique dynamically molding of the orthotic to provide the desired support for most biomechanical movements of the foot of the user. The orthotically dynamic function of the counter supportive frame is the essential foundation needed to derive this perpetual dynamic molding function by the action of the foot anatomy to effectively massage the compound into the most desired position.

[0078] The vertical components of the soft center of pressure channels attract and irrigate the compound away from the bony prominences to comfortably fill, surround and support the empty spaces underfoot. The subtleties of the continuously changing shape of the foot is captured at every moment and in every type of weight bearing.

[0079] The structure of the individual components as well as additional embodiments are discussed in greater detail below:

[0080] *Counter Frame Design*

[0081] As discussed above, the counter frame 12 of the above described preferred embodiment provides the support against which the moldable paste is kneaded or molded. In a preferred embodiment, the counter frame 12 is formed form EVA and polyethylene foams. These foams are slit into desired thicknesses, such as 3 7 millimeters. These foams are then precut into patterns to fit into their respective mold sizes. The pieces are then heated to soften and then pressed into their respective shapes. This forms the pre-molded cradle.

[0082] *Heel Stabilizers*

[0083] It is envisaged that for heavy duty use, the sidewalls 24 of

the insole may be reinforced by inserts of a tough resilient material, e.g., composite materials. Fig. 12 shows a heel stabilizer 60 which may be used either as a reinforcement of the heel portion of the counter frame, or independently, to provide support and reinforcement for a conventional foam or pre-molded insole.

[0084] The heel stabilizer 60 is made of a substantially rigid, hard, elastic plastic material formed to the same shape as the rear of the counter frame 12. Preferably, the heel stabilizer is fabricated in a catalyzed resin of a type which is unaffected by the constant heating and cooling of the moldable paste. Examples of such materials include such materials as nylon, polyethylene, Pebax from Dupont, or pre-assembled and pre-molded hybrid carbon fiber glass composites. Other materials may be used as well.

[0085] The base of the heel stabilizer 60 has a cut-out 62 which corresponds in shape and position to the thinned portion 26 of the counter frame 12. The underside of the heel stabilizer preferably is provided with flexible ribs 64, 66, 68 in a similar manner to the ribs 50, 52, 54 provided on the underside of the counter frame 12. The ribs 64 - 68 are designed and positioned, and function, in the same manner as described with reference to the ribs 50 - 54.

[0086] If the heel stabilizer is used in combination with a counter frame, it is simply placed over the rear portion of the counter frame and secured in position, e.g.,by gluing or thermal forming. The use of the heel stabilizer in combination with the counter frame accentuates the effect of the portion 26 of the counter frame and makes the combined insole both effectively narrower and more supportive of the foot.

[0087] *Stabilizer Spring*

[0088] Another preferred embodiment of the present invention includes a composite leaf spring system to provide shock absorption and control properties. This leaf spring system reinforces the contours of the counter frame to avoid permanent deformation and to add a specific dynamic response and spring return effect, and to further enhance the orthotically dynamic response behavior.

[0089] In a new and more advanced embodiment a thermally cured (pre-impregnated catalyst and adhesive) carbon-Kevlar-glass composite leaf spring system is used. This can be inserted into the molds directly under the existing foam cradle laminates, or sandwiched between the laminating foams during the compression injection molding process.

[0090] By pattern design and weave bias the designer can manage the activity, performance and endurance of the foot precisely; support, absorb and rebound the natural flexing kinematics of the foot; the specific dynamic response (rate of loading) rates required of each activity; design according to the weight of the individual and activity demands. This principle is possible by following the concept that, while all feet are different, bio-mechanically they are the same and require the same needs.

[0091] These pre-impregnated temperature cured woven composites are formed by carefully selecting the weave bias accordingly to create the desired torsional and linear flexural dynamic properties. These patterns are designed in the shape of singular battens or from special horse shoe like patterns. The separate pre-molded battens are pre-molded in assorted stiffness and selected according to the weight and performance demands of the person. These can be cemented to the underside distal aspect of the pre molded cradle, or inserted into pre embossed sleeves to ensure proper positioning. One arm of the U can be threaded through slits in the other arm to position and stabilize the overlap, and the respective bias of the weave. The shape created is similar to a sideways 8 shape. The

bias of the woven composite material is selected, cut and bonded so that at the overlap their interrelationship creates a second specific structural flexural and torsional behavior to support the foot.

[0092] This pre-cut horse shoe is turned into the sideways 8 piece and is placed into the mold, under the assembled foam laminates, or between them. When the molds are closed and compressed the pre-heated temperature of the foams cures the composites in the shape pre-determined by the mold. In the case of injection or pour mold the parts are also positioned before the mold is closed and then is either filled or injected with expanding foam.

[0093] When the U wings of the horse shoe pattern are overlapped, a tear drop shape develops inside the curve as the outside border of the curve raises simultaneously to create an intrinsic heel cup that compliments the essential deep heel cup shape of the pre-molded cradle. This overlapping method creates a heel cup without the creases, folds or distortions that develop when linear materials adapt to the deep and compound curves of the molds. The curved shapes and dynamic response properties can be created according to the bias tailoring of the woven patterns and the function evolves when the thermally sen-

sitive material is activated with heat and cures.

[0094] The uncured soft feather spring materials are cured by the ambient heat of the foams. The horse-shoe parts or battens are assembled in the molds as rigid pre molded parts or inserted as soft materials into the molds. The parts can be inserted into the molds under the foam parts, or between the foam laminates for compression molding. In the case of pour molding or injection molding the parts would be inserted into the molds before they are closed and the foams injected.

[0095] The hole created in the base of the heel cup then acts as a Belleville Spring shock absorber. This can be supplemented by a secondary carbon compound Belleville Spring to interface the first cup hole and thereby further enhance the shock absorbing and dynamic response qualities of the pattern, as needed for different activities and personal preferences.

[0096] In this way the composite feather spring laminates system is imbedded directly into the foam molded structure, to manage the performance dynamic of the resulting device. The foams act as comfort padding and as a retainer between the cured composites and the foot of the wearer.

[0097] The previously flat U-shaped matrix cures and adopts a

three dimensional curved shape of the mold to complement the external foam supportive shapes. The result is a more lively, resilient and infinitely more durable device with unique support and performance.

[0098] The tailoring the bias of the flexible woven composite material can be done so that when the flat horseshoe wings are overlapped (in pretzel fashion) their opposing ends bond together and create a sideways pattern. A three dimensional tear drop shape and funnel develops inside the curve as the outside border of the curve raises to create a more functional heel cup to be imbedded into the foam laminates to complement the bubbles and center-of-pressure channel.

[0099] The deep heel cup created is an effective form of a shock absorbing Belleville spring. This further compliments the essential of the pre-molded cradle and supplements the supportive shapes of the final molded foam counter frame to result in a more lively, resilient and infinitely more durable device with unique support and performance qualities.

[0100] The bonding at the overlap of the sideways 8 weave creates a second specific reinforced laminate with structural, flexural, torsional and elasticity components available to

the discretion of the designer. One important consideration is under the sustentacum tali of the calcaneus, which is in turn aligned directly under the weight bearing ankle and lower ankle joints. This allows the designer to create a predetermined dynamic response and stability for the foot to effectively flex and absorb, as if walking or running in sand, while also directing the course of weight bearing more naturally, and to manage stability at every point in the weight bearing cycle.

[0101] In this new application the dynamic forces applied by some feet transfer directly through the compound and tend to deform the structure and shape of the stabilizing counter-cradle. Therefore the cradle requires particular reinforcement to resist otherwise uncontrollable compression and deformation of the counter shapes that are essential for the irrigation supportive dynamic of the device.

[0102] This feather spring effectively flexes to absorb and direct the course of motions naturally, designed according to the pre-determined bias lay up of the composite glass weave, and then springs back to the original neutral position according to the desired dynamic response. The dynamic response and durability of the feather springs hybrid glass design is important in establishing long term control and

stability of the desired orthotically dynamic behavior and the biomechanically sound function of the kinematic device.

[0103] *Alternative Stabilizer Embodiment*

[0104] An alternative embodiment to the above described stabilizer system is illustrated in Figures 13 18. The stabilizer system 100 of this preferred embodiment includes a cradle or counter frame 110 beneath the contact layer or insole 102. The cradle 110, of this preferred embodiment, is formed from a tough resilient material, such as a carbon composite. The number of layers of fiberglass or other composite materials may be varied to provide the desired attributes depending on the weight and size of the user. The cradle 110 includes side flanges 112, 114 extending upwardly adjacent the heel portion 104 of the insole. The cradle also includes cavity 116 that lies substantially underneath the heel portion 104 of the insole. A flexible arch bridge 118 is formed in the mid portion of the cradle 110 as well.

[0105] In use, the cradle 110 extends beneath the insole 102 so that the side walls 106, 108 of the insole are surround by the side flanges 112, 114 of the cradle adjacent the heel portion 104 and the cavity portion 116 of the cradle ex-

tends beneath the heel portion 104. These details are shown in Figures 17 and 18. Figure 17 illustrates the unweighted heel of the user. The orthotic cradle 110 provides a slightly rounded heel base that along with the lofted arch bridge 118 allows the cradle 110 to roll and adapt as well as move and flex due to the various foot shapes and the dynamics from the biomechanical movement of the foot in the shoe. The insole or blank of the shoe rests on the 120, 122 of the cradle as shown in Figures 17 and 18.

[0106] As the heel is weighted, shown in Figure 18, from the movement of the user, the heel portion 104 of the insole or blank is forced down against the cradle 110 as indicated by the downward arrows. The cavity 116 is flattened and the side flanges 112, 114 are pivoted inward as shown by the arrows. This also effectively decreases the width of the heel portion of the shoe thus providing additional support at this time. The greater the loading, the increase in the support and stabilization of the heel. This feature may be used alone or in combination with the dynamic molding features of the above described embodiments.

[0107] Vertical stabilizers may also be added around the heel

portion to contain the heel tissue of the user as well as the foam material of the insole or blank of the shoe. This will further increase the stabilizing effect of the cradle.

[0108] *Moldable Compound*

[0109] The moldable paste of the preferred embodiment is a high-viscosity paste with a consistency similar to that of very heavy grease, which will flow slowly even at normal operating temperatures, i.e., in close contact with the skin of the user, and therefore at a temperature typically in the range of 35 degrees C 40 degrees C. A paste which has too high a viscosity does not provide adequate cushioning, because it moves so slowly under foot pressure that it is virtually equivalent to a hard surface. Equally, a paste which has too low a viscosity does not provide adequate cushioning, because it simply flows from under the foot immediately any pressure is applied.

[0110] Pastes which have proved satisfactory in use have a viscosity range which gives a flow rate of 1.5 - 7.0 grams per minute, as measured at a temperature approximately equal to body temperature, using ASTM D1238-00 Melt Flow Rates of Thermoplastics by Extrusion Plastometer.

[0111] Preferably, the paste is non-toxic, so that there is no risk in the event of the sack accidentally being punctured.

Preferably also, the paste can be heated by microwave radiation and has good heat exchange and retention properties so that it is feasible to pre-heat and soften the orthotic device to approximate skin temperatures before use. However, it is important that the paste is not too stiff when it is cold, or the insole will be uncomfortable and ineffective when used without heating because the paste will not flow properly to provide the required cushioning effect, and it will take too long for the body heat of the user to bring the paste up to the required temperature.

[0112] One suitable moldable paste constituent has been found to be a microwaveable compound sold under the trade mark by Lan Sri, (Treviso, Italy), that is mixed with mineral or vegetable oil and a granulated cork filler to make a suitable paste for the present invention. One formulation which has been found suitable in practice is made in the following manner: an oil mixture consisting of three parts by weight vegetable oil and one part by weight mineral oil is prepared; the oil mixture is then mixed with medium quality grade/size cork particles that average about 1mm in diameter, in the proportions one part by weight oil mixture to six parts by weight cork particles. The resulting oil/cork mixture is blended in a ratio of equal parts by

weight with a thermal exchange compound of the type described and claimed in the U.S. patent No. 5,478,988 and No. 5,494,598.

[0113] However, if it is not necessary for the moldable paste to be microwave visible, there is no requirement that the orthotic can be heated by means of microwaves, then the thermal exchange component can be omitted and the moldable paste formed simply from the oil mixture and cork particles as described above and the paste softened through the warmth of the body.

[0114] The moldable paste of a preferred embodiment includes a cork binder consisting by weight of 3 parts vegetable oil, and 1 part mineral oil. These materials are mixed, by weight, 1 part of the binder oils into 6 parts of the medium quality grade and size of cork particle. This binder and filler formulation is then blended, in a ratio of 1:1 by weight, with the thermal exchange component.

[0115] The thermal exchange component by itself has no practical application as a dynamic molding or fitting medium. It is the blending of the two components that creates the microwave visible and dynamic molding qualities in one medium.

[0116] The composite material is organic and biodegradable so

there is no hazard in exposure or handling of the material. The result is a non-toxic, bio-degradable, environmentally safe, recyclable composition that performs according to the most desirable spontaneous molding dynamic in a large variety of applications. Unlike two component resins there are no problems of proper mixing or time constraints of pot life and the respective chemical volatility. When properly sealed from air and evaporation, the compound can be subjected safely and effectively to an unlimited number of heating treatments for activating the molding dynamic and heat exchange properties. Likewise the compound does not have a confined shelf life time.

[0117] The performance of the functional fitting compound, when sealed in a laboratory test sample envelope, 10cm x 15cm consists of 2mm EVA-CORK foam, has the capacity to accumulate heat from 30 seconds in a 750 watt microwave oven. Then when set in an insulated box controlled at 0°C, to simulate winter conditions in ski boots, the core temperature of the compound begins at 120°C, and then after 5 minutes stabilizes at 90°C for 100 minutes.

[0118] The structural and insulative properties of the EVA-Cork

Foam is a proprietary formulation and quality prepared by FriuliRubber Company, Udine, Italy. It is a base of expanded EVA foam blended with approximately 10 percent high grade granulated cork, which when results in a favorably resilient texture to the hand and substantial resistance to compression set and constant heating.

[0119] Another suitable foam backing lining for the leather liner material that interfaces the foot is neoprene rubber purchased from Spenco Corporation, Waco, Texas. Both foams have a texture that is excellent for an agreeably comfortable and soft feel that does not compression set with extended use and is unaffected by the constant heating and cooling of the dynamic molding compound.

[0120] The neoprene rubber or eva-cork is slit into 1mm sheets to minimize volume while retaining the appropriate surface texture. The neoprene foam also possesses an agreeable resistance to stretching to help stabilize the leather or other top surface materials from stretching or slipping over the compound.

[0121] The eva-cork foam or neoprene is laminated under to the chosen top cover liner. This preferred embodiment uses expanded (closed cell foam) EVA (Ethyl Vinyl Acetate) laminated with polyethylene foams to create the most desir-

able properties in comfort, lightweight, durability and resistance to compression set. Of course other foams, particularly polyurethane and latex rubber, can be used to derive other mechanical and physical properties.

[0122] The compound may be extended under the ball of the foot and sulcus of the toes. Also the compound may be stopped behind metatarsal heads where desired by laminating the cork foam or neoprene to the counter cradle and using a soft memory foam under the sulcus to adapt to the pressures and supportive needs of the toes. The consideration may be for thinner materials under the toes in fitting into some shoes and the space consumed by the thicknesses of materials.

[0123] Softening the composite in a microwave oven is an invaluable tool for activating the fitting process, to mold to the shapes and dynamics of the foot in situ. Initial molding can be activated as instantly as taking only 10 to 12 active steps. It is important to only heat the microwave visible compound and not to affect the surrounding cradle foams that will deform with other forms of heating.

[0124] Additionally, the self-molding compound has the capacity to accumulate, stabilize temperature and exchange heat over an extended time period. When the accumulated heat

wears out a thermal exchange activates between the compound and the body heat, trading and balancing temperature back and forth at around 32°C.

[0125] It appears that when the body thermostat is given enough time, the 90 minutes to adapt to the stabilized temperature of the compound under foot it is able to regulate the temperature as the compound cools. The foot then recharges compound and then the body thermostat turns off to accept heat back from the compound. This ebbing and flooding of calories is physically detectable.

[0126] This feature is invaluable in many everyday winter situations and for the relief of medical pathologies (such as footwear for diabetics). The devices can be heated numerous times every day before inserting them into shoes and boots.

[0127] The capacity or qualities are not diminished with repeated heating. The devices can also be deep frozen and inserted into shoes to offer cooling relief for about 30 minutes in very hot weather.

[0128] The preferred embodiment of the present invention is not limited to a singular definition of the foot in one static position, which may be considered academically correct. Instead the foot is now able to create a constantly chang-

ing variety of academically correct neutral and locked definitions itself, depending on the dynamics of each foot and each activity. The dynamic response behavior is made possible by the essential irrigation dynamic in addition to softening by microwave heating.

[0129] The supportive shapes are constantly changing and responding to all aspects of gait; twisting, edging, inversion and eversion, absorption and propulsion. Without exception the orthotically dynamic molding kinetics of the device encourages an athletic behavior and response in all feet, and with many favorable physiological manifestations of improved performance, reduced fatigue and injury.

[0130] *Alternative Envelopment Embodiment*

[0131] In another preferred embodiment of the present invention, the sacks are subdivided into compartments, such as by vertical stitching of the two layers of the compound retaining envelope (sacks 16, 18) to allow the two materials to be separated a specified amount. It is to be expressly understood that this is a feature of one preferred embodiment and the present invention is not limited to this feature.

[0132] Vertical stitching separates and controls the space be-

tween the materials and displacement of the compound also permits the building of effective irrigation channels and static flow control pockets and release valves. At the same time this eliminates the problems of recesses, folds and lumps common with normal stitching or welding, as well as stabilizing the horizontal slipping between the two materials due to lubrication by the compound components.

[0133] In this preferred embodiment, the foot develops and concentrates the personalized shape automatically where the support is needed most and according to the particular activity. Therefore the previous problems of dynamic molding have now been solved and the most desired effect is achieved that heretofore was not possible.

[0134] In particular, this preferred embodiment provides the compound hermetically sealed within an envelope and contained within the pre molded counter frame. The pre molded counter frame topography and deformation dynamic when under pressure are designed to increase the three dimensional supportive shape according to the demands exerted by the anatomy.

[0135] The envelope or sack of this preferred embodiment may be lined with the desired impervious and friction surface

textures to facilitate or hinder the rate of flow of the compound, when sandwiched between the counter frame and outer lining material. The outer lining material, such as shoe quality leather, is laminated with a material such as thin neoprene foam to control the stretching of the leather and to enhance the user friendly feeling against the foot.

[0136] Alternative Contact Layer Embodiment

[0137] In another preferred embodiment, the top surface outer lining materials create a particular surface tension due to their elasticity that affects its dynamic performance of the compound. Therefore the choice of top surface materials needs to be coordinated with the formulation of the compound.

[0138] The outer lining material and laminate is stitched and cemented around the periphery of the stabilizing frame in this preferred embodiment. The personalization port is injected with a predetermined amount of compound and then sealed with a simple 5mm long by 4mm diameter plastic hole plug. The compound is pre-molded in the initial ready to wear shape. The device is now ready for packaging.

[0139] These and the other descriptive embodiments were pro-

vided only for exemplary purposes and are not meant to limit the scope of the claimed inventions. Other embodiments of the present invention are considered to be within the scope of the claimed inventions, including not only those embodiments that would be within the scope of one skilled in the art, but also as encompassed in technology developed in the future.